DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10518 and CMS- 10340]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10518	Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration
CMS- 10340	Collection of Encounter Data from MA Organizations

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of

information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request*: Extension without change of a currently approved collection; *Title of Information Collection*: Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration; *Use*: Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for persons with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer it if the person is not homebound and otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office or in an outpatient hospital setting.

The Medicare IVIG Demonstration application requests basic demographic information necessary to determine eligibility for participation in the demonstration. This information is used by CMS' implementation support contractor to determine eligibility for the demonstration and to set up a demonstration eligibility record that is used by the Medicare claims system when processing claims for demonstration services.

The application also includes some questions about how and where the beneficiary is currently receiving immunoglobulin and related services. This data is being used by the evaluation contractor to conduct its evaluation and to better understand which beneficiaries are electing to enroll in the demonstration. *Form Number*: CMS-10518 (OMB control number: 0938-1246); *Frequency*: Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 6,500; *Total Annual Responses*: 6,500; *Total Annual Hours*: 1,625. (For policy questions regarding this collection contact Debra K. Gillespie at 410-786-4631.)

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection:* Collection of Encounter Data from MA Organizations *Use:* Section 1853(a)(3)(B) of the Act directs CMS to require MA organizations and eligible organizations with risk-sharing contracts under 1876 to ''submit data regarding inpatient hospital services ... and data regarding other services and other information as the Secretary deems necessary'' in order to implement a methodology for ''risk adjusting'' payments made to MA organizations and other entities. Risk adjustments to enrollee monthly payments are made in order to take into account ''variations in per capita costs based on [the] health status'' of the Medicare beneficiaries enrolled in an MA plan.

CMS collects encounter data for beneficiaries enrolled in MA organizations, section 1876 Cost Health Maintenance Organizations (HMOs)/Competitive Medical Plans (CMPs), Programs of All-inclusive Care for the Elderly (PACE) organizations, and MMPs. For PACE organizations and MMPs, encounter data serves essentially the same purposes as it does for the MA program (for Part C and Part D risk adjustment). To 1876 Cost Plans that offer Part D coverage, CMS makes risk adjusted, capitated monthly payments for Part D.

MA organizations, Part D organizations, 1876 Cost Plans, MMPs and PACE organizations must use a CMS approved Network Service Vendor to establish connectivity with the CMS secure network for operational purposes. Once connectivity is established, these entities must submit required documents to CMS's front-end contractor to obtain security access credentials. *Form Number*: CMS- 10340 (OMB control number: 0938–1152); *Frequency*: Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 733; *Total Annual Responses:* 1,068,204,429; *Total Annual Hours:* 35,618,366. (For policy questions regarding this collection contact Michael P. Massimini at 410-786-1560.)

Dated: February 9, 2021.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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